

**510(k) SUMMARY****Diagnostic Photonics Foresee (4C) Imaging System****1. Basic Information-Submitter:**

Submitter: Diagnostic Photonics, Inc.
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Date Summary Prepared: March 6, 2014

2. Device Name:

Trade Name: *Foresee (4C) Imaging System*
Common Name: Optical Coherence Tomography Scanner
Classification Name: Ultrasonic pulsed echo imaging system
Regulation Number: 21 CFR 892.1560
Product Code: NQQ
Classification: Class II

3. Predicate Devices:

Imalux OCT Imaging System – K033783
Michelson Diagnostics VivoSight Topical OCT System – K093520

4. Indications for Use Statement:

The Foresee (4C) Imaging System is intended to be used as an imaging tool in the evaluation of external human tissue microstructure by providing two-dimensional, cross-sectional, real-time depth visualization.

5. Technological Characteristics:

The Foresee (4C) Imaging System uses optical coherence tomography (OCT) to create images of tissue. OCT is an imaging technology similar to ultrasound except that images are formed using reflected light rather than reflected sound. In place of sound waves, OCT uses a near-infrared beam of light that penetrates tissue. The light reflects off of changes in tissue microstructure. Using the principles of low-coherence interferometry, a technique that measures the interference of light from a sample arm and a reference arm to create an image, OCT produces a high-resolution depth profile. Scanning the beam across tissue produces a detailed, two-dimensional image of tissue microstructure morphology.

The Foresee (4C) Imaging System uses a broadband, swept optical source and a fixed reference arm to acquire imaging data in the frequency domain. The Foresee (4C) Imaging System has a handheld probe for the scanning of tissue. The probe has a fixed focal depth with a correction for beam diffraction employing a physics-based, software signal processing technique.

The Foresee (4C) Imaging System consists of a cart-mounted imaging console with an isolation transformer; a foot pedal; a handheld imaging probe with a single-use non-sterile disposable probe tip; an imaging module containing a light source, interferometer, and detector; and an imaging computer that implements physics-based software signal processing; and dual monitors for image display. The system user interface allows the viewing, capture, review and export of images.

6. Performance Data:

The Foresee (4C) Imaging System is designed and tested to be in compliance with international standards (noted in **Table 1** on the following page) concerning safety for electrical and mechanical safety, electromagnetic emissions and susceptibility, biocompatibility, disinfection, and laser safety. Key features of the system design related to electrical safety and electromagnetic compatibility include an isolation transformer for system power; a shielded and grounded enclosure meeting requirements for fireproof enclosure; and a double insulated probe housing and cable for patient protection. The system has been tested for electrical and mechanical safety for Medical Electrical Equipment and for electromagnetic compatibility as specified in **Table 1** on the following page. The system uses a laser that is limited in power to meet the requirements of a class 1 laser device in accordance with IEC 60825-1:2007.

The handheld probe has been designed to be a reusable component and to support cleaning and low level disinfection. A process has been developed and validated for reprocessing of the reusable handheld probe (see details in **Section XVI**). The single use probe tip has been designed using materials that adhere to the requirements for skin surface limited (<24 hours) contact. The complete single use probe tip has been tested for Biocompatibility per ISO 10993 based on the intended use.

The system image performance has been tested to evaluate the in-depth spatial resolution, in-depth image range, lateral spatial resolution, lateral image range and scan linearity deviation. Imaging of tissue of the esophagus, bladder, and colon from healthy New Zealand white rabbit was performed to study the performance of the Foresee (4C) Imaging System in comparison to published predicate data from the Imalux OCT Imaging System and to demonstrate the imaging capabilities of the Foresee (4C) Imaging System for the visualization of tissue microstructure in tissue specimens. The standards that the system has been tested against assure the safety of the device and are listed on the following page.

Table 1: Relevant International Standards

Safety Testing	Standard
ANSI/AAMI ES60601-1:2005 (IEC 60601-1 3rd Edition)	Medical Electrical Equipment
IEC 60825-1:2007	Safety of Laser Products
AAMI/ANSI/ISO 10993-5:2009	Biological Evaluation of Medical Devices -- Part 5: Tests for In Vitro Cytotoxicity.
AAMI/ANSI/ISO 10993-10:2010	Biological Evaluation of Medical Devices - Part 10: Tests for Irritation and Skin Sensitization.
AAMI/ANSI/ISO 10993-11:2006	Biological Evaluation of Medical Devices -- Part 11: Tests for Systemic Toxicity
IEC 60601-1-2:2007	Medical Electrical Equipment
IEC 61000-3-2:2006	Electromagnetic Compatibility (EMC), Part 3-2
EN61000-3-3:2008	Electromagnetic Compatibility (EMC), Part 3-3

Image performance and in vitro testing have been performed. All components, subassemblies, and/or full devices and systems have met the required specifications for the completed tests above. In all instances, the Foresee (4C) Imaging System functioned as intended and results observed were as expected.

7. Statement on the Status of the Cleaning and Disinfection Validation Studies:

The instructions for reprocessing the device will be validated before the device is marketed according to the FDA email dated March 3, 2014 and phone conference on March 6, 2014. Cleaning validation testing will demonstrate the effective cleaning of devices soiled under repeated use with a test soil including two (2) quantitative test markers. Disinfection validation testing will demonstrate a 6 log₁₀ kill of four (4) test organisms individually. The validation of the reprocessing instructions and the final labeling will be on record at Diagnostic Photonics, Inc. located at 200 South Wacker Drive, 31st Floor, Chicago, IL 60606 and available for inspection; they will be supplied to FDA upon request. The validation will include protocols, specifications, pass/fail criteria, results, and procedures describing when the instructions must be requalified (e.g., if the device is modified).

8. Substantial Equivalence:

The Foresee (4C) Imaging System is as safe and effective as the Imalux OCT Imaging System and the Michelson Diagnostics VivoSight Topical OCT System. As shown in Table 2 on the following page, the Foresee (4C) Imaging System has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate devices. The minor technological differences between the Foresee (4C) Imaging System and its predicate devices raise no new issues of safety or effectiveness. Performance data demonstrate that the Foresee (4C) Imaging System is as safe and effective as the Imalux OCT Imaging System and the Michelson Diagnostics VivoSight Topical OCT System. Thus, the Foresee (4C) Imaging System is substantially equivalent.

	Foresee (4C) Imaging System	Imalux OCT Imaging System (K033783)	Michelson Diagnostics VivoSight Topical OCT System (K093520)
Indications for Use	Imaging tool in the evaluation of external human tissue microstructure by providing two-dimensional, cross-sectional, real-time depth visualization. <i>Intended Use:</i> Imaging of external human tissue microstructure (non-sterile)	Imaging tool in the evaluation of human tissue microstructure by providing two-dimensional, cross-sectional, real-time depth visualization. <i>Intended Use:</i> Imaging of human tissue microstructure (sterile and non-sterile)	Indicated for use in the two-dimensional, cross-sectional, real-time imaging of external tissues of the human body <i>Intended Use:</i> Imaging of external human tissue (non-sterile)
Measurement Technique	Optical Coherence Tomography	Optical Coherence Tomography	Optical Coherence Tomography
Radiation Type	Near-Infrared Low-Coherence Beam	Near-Infrared Low-Coherence Beam	Near-Infrared Low-Coherence Beam
Optical Source	Swept Source	Super Lumeniscent Diode (SLD)	Swept Source
Near-Infrared Wavelength (700-1400 nm)	Yes	Yes	Yes
Reference Arm	Fixed reference arm, frequency-domain signal acquisition	Scanned reference arm, time-domain signal acquisition	Fixed reference arm, frequency-domain signal acquisition
Optical Radiation Safety	Safe for Indicated Use Class 1 Laser	Safe for Indicated Use Class 3R Laser	Safe for Indicated Use Class 1 Laser
Lateral Range (Imaging Aperture)	9.6 mm	2 mm	5 mm
In-Depth Range (z-axis)	>2.1 mm (in air)	2.2 mm (in air)	~1.2 – 2 mm
Axial Resolution (z-axis)	(<20 μ m in air)	10-20 μ m [\leq 21 μ m (in air)]	< 5 μ m
Lateral Resolution (x-axis)	<20 μ m	\leq 50 μ m	< 7.5 μ m
Scanning Pattern	Line	Line	Line
Scan Time	>7 frames/sec	>1 sec/frame	> 6 frames/sec
Information Display	Patient ID Operator name Date and time stamp Image comments Hospital/Institution Name	Patient name Operator name Date and time stamp Image comments	Patient name and ID Clinician ID Date and time stamp
Diffraction Compensation	Uses a single fixed focal depth imaging beam and corrects for beam diffraction with a physics-based software signal processing technique	Uses a single fixed focal depth imaging beam	Uses four separate imaging beams, each focused at a different fixed depth in tissue, and corrects for beam diffraction with software-based signal processing that constructs a merged image
Electrical Voltage Frequency	120/240 V 50/60 Hz	90-132 V, 198-264 V 50/60 Hz	116-264 V 50/60 Hz
Computer-Controlled, IBM-PC Compatible	Yes	Yes	Yes
Input devices: Keyboard Pointing Foot Pedal	Yes Yes Yes	Yes Yes Yes	Yes Yes Yes

Table 2: Summary of Technological Characteristics

9. Conclusion

Diagnostic Photonics, Inc. has demonstrated that the Foresee (4C) Imaging System has the same intended use and is substantially equivalent to the predicate devices listed above. The Foresee (4C) Imaging System also complies with recognized standards and guidelines for electrical safety, laser safety, cleaning and disinfection, and biocompatibility. Non-clinical tests demonstrate that the device is as safe, as effective, and performs as well as or better than the predicate devices listed above.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-6609
Silver Spring, MD 20993-0002

March 17, 2014

Diagnostic Photonics Incorporated
% Ms. Janice Hogan
Hogan Lovells US LLP
1835 Market Street, 29th Floor
Philadelphia, Pennsylvania 19103

Re: K133209
Trade/Device Name: Forsee (4C) Imaging System
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: Class II
Product Code: NQQ
Dated: February 14, 2014
Received: February 20, 2014

Dear Ms. Hogan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Felipe Aguel

for

Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page

510(k) Number (if known)

K133209

Device Name

Foresee (4C) Imaging System

Indications for Use (Describe)

The Foresee (4C) Imaging System is indicated for use as an imaging tool in the evaluation of external human tissue microstructure by providing two-dimensional, cross-sectional, real-time depth visualization.

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

Neil R Ogden -S

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For BSA

(Division Sign-Off)

Division of Surgical Devices

510(k) Number K133209

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